

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Phentermine with topiramate for the treatment of obesity and overweight

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of phentermine with topiramate within its licensed indication for the treatment of adults who are obese or who are overweight and have weight-related co-morbidities.

Background

Obesity is a chronic condition characterised by increased body fat, which poses a significant risk to health. The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. In adults of European family origin, overweight is typically defined by a BMI of 25 kg/m² to 29 kg/m² and obesity by a BMI of 30 kg/m² or more (an appropriate adjustment of BMI for other ethnic groups is necessary). People with obesity are at increased risk of developing cardiovascular disease, type-2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension and dyslipidaemia (abnormal levels of fats in the blood). In 2009, almost two-thirds of adults in England were classed as being overweight or obese and almost a quarter of adults were obese.

Current treatment of obesity includes dietary and lifestyle advice, pharmacological treatments, and surgical intervention. NICE has produced several public health guidance documents which address weight management. NICE clinical guideline 43 for the prevention, identification, assessment and management of overweight and obesity in adults and children recommends that drug therapy with orlistat should only be considered after dietary, exercise and behavioural approaches have been started and evaluated. The clinical guideline also recommends that surgical intervention (such as bariatric surgery) is considered as a first-line option for adults with a BMI of more than 50 kg/m². For adults with BMI of more than 40 kg/m² or BMI of more than 35 kg/m² with other significant obesity-related disease (such as type II diabetes) it is recommended that surgery is considered only after all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate weight loss for at least 6 months.

The technology

Phentermine with topiramate (Qsiva, Vivus) is an oral low-dose combination of immediate-release phentermine and prolonged-release topiramate. Phentermine is an appetite suppressant and topiramate is an anti-convulsant with weight loss properties.

Phentermine with topiramate does not have a UK marketing authorisation. It has been studied in clinical trials in combination with behaviour modification compared with placebo in obese (BMI at least 30 kg/m²) and overweight adults with weight-related co-morbid conditions (no BMI limit) such as hypertension, type 2 diabetes, dyslipidemia, or central adiposity (abdominal obesity).

Intervention(s)	Phentermine with topiramate in combination with behaviour modification
Population(s)	<ul style="list-style-type: none"> • Obese adults • Obese or overweight adults with weight-related comorbid conditions
Comparators	Orlistat (high dose and low dose preparations) in combination with behaviour modification
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • weight loss • cardiovascular events • change in concomitant medication • mortality • adverse effects of treatment • health-related quality of life. <p>Where information on clinical endpoints is unavailable, consideration may be given to surrogate end-points such as:</p> <ul style="list-style-type: none"> • Glycated haemoglobin (HbA1c) • cholesterol levels and lipid profiles (including LDL and HDL) • blood pressure • insulin resistance

<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> • number and type of weight-related co-morbid conditions • body mass index • presence or absence of type 2 diabetes <p>The need for different BMI ranges for people from certain ethnic backgrounds will be considered.</p>
<p>Related NICE recommendations</p>	<p>Related Technology Appraisals</p> <p>Technology Appraisal in preparation, 'Lorcaserin hydrochloride for the treatment of obesity and overweight'. Earliest anticipated date of publication end 2013.</p> <p>Related Clinical Guidelines</p> <p>Clinical Guideline 43, December 2006. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. Partial review in preparation. Earliest anticipated publication date tbc.</p> <p>Related Public Health Guidance</p> <p>Public Health Guidance 2, March 2006. Four commonly used methods to increase physical activity. Review decision date: March 2013.</p> <p>Public Health Guidance 8, January 2008. Physical activity and the environment. Review decision date: February 2014.</p> <p>Public Health Guidance 13, May 2008. Promoting physical activity in the workplace. Review decision</p>

	<p>date: July 2014.</p> <p>Public Health Guidance 27, July 2010. Dietary interventions and physical activity interventions for weight management before, during and after pregnancy. Review decision date: July 2013.</p> <p>Public Health Guidance in preparation: BMI and waist circumference – black and minority ethnic groups. Earliest anticipated date of publication: June 2013.</p> <p>Public Health Guidance in preparation: Obesity – working with local communities. Earliest anticipated date of publication: November 2012.</p> <p>Public Health Guidance in preparation: Overweight and obese adults - lifestyle weight management. Earliest anticipated date of publication: October 2013.</p>
--	--